K030363

510(k)
Ebit Sanità Org@nizer Software
Ebit Sanità, S.p.A.

MAR 27 2003

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle Densmore, Official Correspondent
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Indianapolis, IN 46250
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Contact Person: Colleen Hittle Densmore

Date: January 15, 2003

807.92(a)(2)

Trade Name: Ebit Sanità Org@nizer Software

Common Name: System, Image Processing

Classification:
Regulatory Class: II

	FR Number	Product Code
Image Processing System	892.2050	90-LLZ

807.92(a)(3)

Predicate Device(s)

Applicare	Radworks Medical Imaging Software W/ Quality Control Module	K982862

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k)
Ebit Sanità Org@nizer Software
Ebit Sanità, S.p.A.

807.92(a)(4)

Device Description

The Ebit Sanità Org@nizer software is a medical Image Management software device used for digital acquisition, viewing, processing, archiving, reporting and communicating ultrasound studies.

807.92(a)(5)

Intended Use(s)

The Ebit Sanita Org@nizer software is intended to be used for digital acquiring, viewing, processing, archiving, reporting and communicating ultrasound medical studies by qualified medical professionals, after proper installation on an appropriate hardware platform.

Comparison Chart for Substantial Equivalence

Product	Ebit Sanità Org@nizer Software (This submission)	Applicare Medical Imaging Radworks Medical Imaging Software with Quality Control Module K982862
Classification	892.2050 LLZ Class II	892.2050 LLZ Class II
Intended use	The Ebit Sanità Org@nizer software is a medical image management software device intended to be used for digital acquiring, viewing, processing, archiving, reporting and communicating ultrasound medical studies by qualified medical professionals, after proper installation on an appropriate hardware platform	The RadWorks Quality Control Module is intended to be used by authorized staff to perform various quality control operations on RadWorks imaging studies before they are made available to other locations on the network. These operations include confirming or editing patient characteristics, reviewing the status history of the study, adding or removing images, combining with another study, renumbering images, editing patient orientation information, and setting or editing routing information.
Graphic User Interface	Yes	Yes
Platform	PC	PC
Operating System	Microsoft Windows based	Microsoft Windows based
Display Resolution	1280x1024	2048x2560
Image Resolution	From 8 bits grayscale and 24 bits color	From 8 bits, 256 levels to 24 bits color
Image Communication	DICOM Compliant	DICOM Compliant
Image Compression	No image compression techniques are utilized	Jpeg Loss-less; Jpeg lossy
Image Archiving (Hard Disk)	Yes	Yes
Image Archiving (Removable Media)	CD-R;; DVD-R, other Dicom Entities	CD-R; MOD; DVD-R, other Dicom Entities
Image Review	Still frame, Cine-loops, Window-level, Zoom, Panning, Configurable layout	Still frame, Cine-loops, Window-Level, Zoom, Panning, Configurable layout
Image Processing	Annotation: , text, lines, Measurements: Distance, area, perimeter, velocity	Annotation: arrows, text, lines, Circles Measurements: distances, angles, pixel values, pixel distribution, grey level statistics
Image Database	Yes	Yes
Image Management	Uncompressed / JPEG Lossy / RLE Loss-less	Uncompressed / JPEG Lossy / JPEG Loss-less

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2003

Ebit Sanita, S.p.A.
% Ms. Colleen Densmore
The Anson Group
7229 Castleway Drive
INDIANAPOLIS IN 46250

Re: K030363
Trade/Device Name: Org@nizer Version 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 31, 2003
Received: February 4, 2003

Dear Ms. Densmore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Applicant: Ebit Sanità S.p.A.

510(k) Number (if known): K030363

Device Name: Ebit Sanità Org@nizer Software

Indication For Use:

The Ebit Sanità Org@nizer software is a medical image management software device intended to be used for digital acquiring, viewing, processing, archiving, reporting and communicating ultrasound medical studies by qualified medical professionals, after proper installation on an appropriate hardware platform.

This medical device is intended for the sole use of digital acquiring, viewing, processing, archiving, reporting and communicating digital ultrasound studies. It does not have any influence in the way the medical image is produced, nor it is intended to control ionizing emissions or monitor vital physiological processes. The medical device is able to manage stand-alone or distributed medical image archives. It specifically provides the following added-value:

- Connecting diagnostic modalities for the purpose of centralising the image archiving for later image viewing, processing and reporting;

- Establishing distributed points of access on conventional PCs for distributed image and report viewing and access.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** Over The Counter _____

(PER 21 CFR, 801.109)

(optional Format 1-2-96)

David G. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030363